

is only most recently that the rejection over Mantelle '022 under 35 U.S.C. § 102(e) has once again been raised.

Applicants have continually emphasized the fact that the claims in Mantelle'022, which are the essential element in the Examiner's contention that the Declaration under Rule 131 is inapplicable and that § 102(e) applies thereto, are different from and not supported by applicants' disclosure. The Examiner has applied the "two-way test" in determining this issue; namely, whether the claims pending in the present application are patentable over claims such as claim 23 of Mantelle '022, and vice versa. See *Winter & Fujita*, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Interf. 1999). From the point of view of claim 23 of Mantelle '022, the invention claimed therein is quite different from that of the presently pending claims in that it is specifically directed to an adhesive polymer which consists of acrylic-based polymers having a specified shear resistance so that they can maintain sufficient tack and shear to remain in place during use. The thrust of the invention of claim 23 is thus to select a particular acrylic adhesive which has certain specific properties in order to allegedly obtain these results. Turning to the claims in the present application, such as claims 84 and 92, these claims are directed to an entirely different invention; namely, one which is primarily based upon the exclusion of certain solvent systems; namely, water and liquids having boiling points below processing temperatures and equal to or greater than the boiling point of the drug itself. Again, a totally different inventive concept is involved, and it is no way based on a determination of the shear resistance of the acrylic polymers hereof.

These differences were, in fact, highlighted during prosecution of Mantelle '022 itself. During that prosecution, a declaration was filed under Rule 132 comparing four acrylic-based pressure-sensitive adhesives; namely, DURO-TAK

87-2979, 87-1297, and 387-2553, as well as DURO-TAK 87-2852, which was said to be the one with high shear-resistance characteristics. The first three adhesives were said to be lower than minimum shear resistance. That declaration thus included a table showing that the first three DURO-TAK adhesives had a shear resistance of 24 and 2 hours, respectfully, at 4 psi at 72°F, but that DURO-TAK 87-2852 was said to be greater than 100 hours at 4 psi at 72°F (50 hours at 8 psi at 72°F). These polymers were then formulated with selegiline base and a silicon pressure-sensitive adhesive (Bio-PSA X7-4501) in the proportions set forth in the following table.

Raw Material	Ex. 1	Ex. 2	Ex. 3	Ex. 4	Ex. 5	Ex. 6	Ex. 7	Ex. 8
Selegiline Base	20	20	20	20	15	15	15	15
Bio-PSA X7-4501*	20	20	20	20	20	20	20	20
Duro-Tak 87-2852	60	-	-	-	65	-	-	-
Duro-Tak 87-2097	-	6-	-	-	-	65	-	-
Duro-Tak 387-2353	-	-	60	-	-	-	65	-
Duro-Tak 87-2979	-	-	-	60	-	-	-	65

\*Silicone PSA, Dow Corning Corp., Midland, Michigan

The shear-resistance characteristics of these materials were then tested, and those with less than 2-3 minutes were generally said to be gummy and oozy compositions. The following table was said to show that Examples 1 and 5 had acceptable shear-resistance values.

<u>Samples</u>	<u>Shear Values</u> <u>(minutes)</u>
1	5.6
2	0.2*
3	0.7
4	0.1*
5	13.9
6	0.4
7	1.4

8

0.1

\*Only one unit tested (samples delaminated/fell apart)

The claims in that application were then amended to include the same shear-resistance values.

Once again, this can be contrasted to the claims in the present application, and it clear that claim 23, for example, in Mantelle '022 does not teach or suggest the invention to which the present claims are directed. There is nothing in claim 23 about the inventive concept of excluding water and certain low volatility solvents from these compositions to obtain the results of the present invention. To the contrary, a totally different invention; namely, selection of a particular adhesive polymer with a particular shear resistance, is the sole invention of that claim. This, however, would not even suggest the use of the very same acrylic polymers excluded from claim 23 in compositions which have these properties by virtue of their exclusion of water and low volatility solvents. Therefore, applying the two-way test referred to by the Examiner, if claim 23 of Mantelle '022 were prior art against the claims in this application, it is respectfully submitted that the present claims would clearly be patentable over this prior art. The prior art (claim 23) would not in any way, shape or form suggest the claimed invention of excluding water and certain low volatility solvents from these compositions in order to obtain the present results. Indeed, claim 23 would, in fact, teach away from this invention because it would clearly teach that using acrylic polymers that do not meet the requirements of claim 23 would not work. To the contrary, however, the present application proves that by employing the claimed invention hereof, it is possible to use many acrylic polymer compositions which would not meet the

requirements of Mantelle '022, but which would nevertheless result in the improved results of the present invention.

On the other hand, if the present claims were prior art against claim 23 of Mantelle '022, it is submitted that claim 23 would clearly be patentable thereover because the claims in this application do not suggest that by merely selecting acrylic polymers meeting specific shear resistance requirements one can achieve the results claimed by Mantelle '022. To the contrary, the present specification is replete with data demonstrating that shear resistance is not a predictable factor in selecting the products of this invention. Products with varying shear resistance properties were tested in this application, and it was found that this was not a critical factor in selecting the improved products hereof. Applicants therefore assert that the two-way test establishes that these are two different inventions and that there would be no interfering subject matter therebetween, that no interference in fact could exist, and that the provisions of 35 U.S.C. § 102(e) should not be applied in this case.

Even understanding all of this, it appears to be the Examiner's position, in view of the sole fact that Mantelle '022 and the present application disclose a single species of acrylic adhesive (namely, DURO-TAK 87-2852), which the Examiner contends could be used in both the claimed invention hereof and that of Mantelle '022, that this rejection is appropriate.

The Examiner cites no authority for the specific rejection over Mantelle '022 under 35 U.S.C. § 102(e), nor the refusal to accept the previously filed Declaration under Rule 131 herein. The rejection itself, however, is clearly based upon a contention that applicants and Mantelle '022 are claiming the "same invention," and therefore Rule 131 does not apply. This, in turn, is clearly based upon the allegation that

the DURO-TAK 87-2852 disclosed in Mantelle '022 is the same as one polymer specified by applicants as being useful in the present application. It is thus the Examiner's position that a single point of overlap between the acrylic polymers within the scope of the claims in Mantelle '022 and the acrylic polymers within the scope of applicant's claims makes it unquestionable that the "same invention" is involved in both cases. The Examiner's position is without support, either legally or logically.

Applicants have described above the many reasons why the claims in this application and those in Mantelle '022 are patentably distinct from each other. On a factual basis, however, attached hereto as Exhibit A is a specification from National Starch and Chemical Co. with respect to that company's Product No. DURO-TAK 87-2852 which specifies that this product has a shear strength of "at least 20 hours at 8 psi." It is therefore unclear whether, by the mere disclosure of DURO-TAK 87-2852 as one embodiment of a suitable acrylic polymer for use in the invention of that patent, that this can be said to clearly establish that the claims of Mantelle '022, such as claim 23, also clearly include this compound. If DURO-TAK 87-2852 is only disclosed in Mantelle '022, but is not claimed therein, there is no barrier to the acceptance of applicants' Declaration under Rule 131. On the other hand, if as stated by the manufacturer of that product, there is a variability in the shear strength of DURO-TAK 87-2852, so that it can presumably be either above or below the limits set forth in the claims of Mantelle '022, the mere disclosure of that compound in Mantelle '022 does not necessarily mean that the claims which ultimately issued in Mantelle '022 actually do incorporate DURO-TAK 87-2852. Thus, even the single point of overlap between these

claims and the claims in the present application as asserted by the Examiner may not actually exist.

Without further authority, the Examiner's position in this case is unsupportable. The attempt to prevent applicants from swearing behind Mantelle '022 based solely upon an alleged coincidence of a single overlapping point with respect to the acrylic adhesive which is allegedly usable in both of these inventions is an entirely inadequate and improper basis for concluding that applicants and Mantelle et al. are claiming the "same invention." This is simply not the case here; applicants could not support the limitations in the claims in Mantelle '022 based on their specification; and there is simply no reason why the Declaration under Rule 131 has not been accepted in this case. If the Examiner refuses to accept this position and persists in this rejection, it is respectfully requested that some authority for this specific position (namely, that a single point of overlap between one of the elements in applicants' claims and the claims in Mantelle '022 (even if one such point does exist — which applicants vehemently deny) establishes that these two patents are claiming the "same invention." It is believed that there is no real authority for this position.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 08/883,075

Docket No.: MTI 3.0-025

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 

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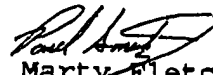
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**National Adhesives**

A National Starch &amp; Chemical Business

National Starch and Chemical Co.  
 Transdermal Technical Service  
 10 Finderne Ave.  
 Bridgewater, NJ 08807  
 Phone: 908-685-7463  
 Fax: 908-575-7288

Customer / Address

Adhesive Specification Sheet	
Date:	2/3/2006
National Approver:	Paul Smutz
National Signature:	
Customer Approver:	Marty Fletcher
Customer Signature:	
Date:	

Mylan Technologies Inc.  
 110 Lake Street  
 St. Albans, VT 05478-2266  
 Attn: Marty Fletcher  
 Fax: 802-527-8151

Product No: 0872852  
 Cust. Prod. No/Desc.:

Product name: DURO-TAK®

The following statement will appear on all COAs:

This COA is generated by SAP. This batch has been reviewed  
 and approved by Quality Control.

This statement is equivalent to a signature release.

Batch 0000000000 / Quantity 0000 LB

Characteristic	Min	Max	Batch 0000000000
SOLIDS, %	31.5	35.5	%
VISC (R3,20,72)	1300	3700	cps
IR SPECTRUM	0.992	1.000	
180° PEEL ADHESION, OZ/INCH	35	75	oz/in
SHEAR, HRS (8PSI)	20	-	hrs.
RESIDUAL 2-EHA, PPM	-	1000	ppm
RESIDUAL MA, PPM	-	1000	ppm
RESIDUAL AA, PPM	-	500	ppm
MANUFACTURING DATE:			

Specification Sheet Only. This is not a COA.